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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,417	02/27/2004	Chien-Hsuan Han	7483/88058	4537

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/787,417	HAN ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments and amended claims filed on 09/28/2007 is acknowledged.

Claim 1 has been amended.

Claims 1-33 are pending in this application and claims 1-33 will be prosecuted on the merits.

2. The Double Patenting Rejection over claims 1-31 of US Patent No. 7,094,427 B2 has been withdrawn in view of Applicants filing of Terminal Disclaimer.

3. The rejection made under 35 USC 112.2 has been withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-6, 16-22 and 24 -33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conte et al. (US Patent No. 6,294,200).

Conte et al. teaches a pharmaceutical tablet capable of delivering active substance(s) according to a predetermined release profile, whereby the tablet is characterized as having (a) a core consisting of three layers, in which 1) the upper layer contains an active substance, which is immediately released; 2) an intermediate layer which determines the time interval between the release of the active substance contained in the upper layer (1) and the lower layer (3); and 3) a lower layer formulated to have release of the active substance with prefixed kinetics and controlled release of the active substance and (b) a coating applied on the lower and lateral surface of the core. Conte et al. teach that various active substances may be employed that include, antiparkinson drugs such as Levodopa, Carbidopa and Benserazide (column 2, line 13 and column 8, line 41).

Example 7 at columns 19-21 exemplifies tablets containing a mixture of anti-Parkinson drugs, Carbidopa and Levodopa having a release profile as shown in Table VII. In order to estimate the release characteristics of the tablets the equipment 2, paddle (described in USP XXII)is used operating at 100 rpm and using deionized water at 37°C as the dissolution fluid. In the preparation of the first granulate for Layer 1, 30 mgs of Carbidopa and 30 mg of Levodopa are used. A second granulate for preparing Layer 3 contains 25 mg of Carbidopa and 100 mg of Levodopa. A coating is also included. The

release profiles of Table VII demonstrate the Time (in mins), the % Carbidopa released and the % Levodopa released. For example, in 15 mins. 53.9% of Carbidopa was released and 21.0% of Levodopa was released. After 30 mins. 55.4% of Carbidopa and 23.0% Levodopa was released and so forth as seen in the Table.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to optimize the release profile of Conte et al. because Conte et al. teaches a release profile which is in close proximity with the release characteristics as claimed. Further, since Conte et al. discloses that such a release characteristics can be obtained in a predetermined times, it would have been obvious to the one of ordinary skilled in the art to optimize the release characteristic with the experimental manipulations at the time the invention was made. Similarly, with regards to claimed ratios and amounts of various active agents, it is the position of the examiner that these parameters would have been within the purview of a skilled artisan at the time the invention was made to optimize with experimental manipulations. . "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The prior art recognizes the art of formulating anti-Parkinson drugs, such as Carbidopa and Levodopa, in a combined dosage form that provides both immediate and controlled-release characteristics. Hence, the instant invention is deemed unpatentable.

Response to Arguments

6. Applicant's arguments filed 09/28/2007 have been fully considered but they are not persuasive.

Applicants argue that " various amounts and release profiles as cited in the prior art is not same as the claimed invention and that optimizing the release profiles would not have been obvious in view of Conte "200 and the reference teaches away from the claimed invention". Applicant's arguments are considered but were not found persuasive. While Conte does not teach the exact amounts or release profiles as claimed, the burden is shifted to Applicant to demonstrate that the invention achieves unexpected and superior results over that of the prior art. As discussed in the rejection above, Conte's reference teaches formulation of immediate and controlled release formulations comprising carbidopa and levodopa. The results provide effective results using various amounts. Various in vitro release profiles are depicted in Table VII. It is therefore position of the examiner that optimization of various amounts claimed and the release profile would have been obvious to one of ordinary skilled in the art at the time of invention by doing experimental manipulations. Applicant is required to present scientific data showing that the specific release profiles claimed provide superior and unexpected results.

The rejection is therefore maintained.

7. Claims 2, 7-15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conte et al. (US Patent No. 6,294,200) in view of Virkki et al. (US

patent No. 6,500,867).

The teachings of Conte et al. have been discussed above.

Conte et al. do not specifically teach COMT inhibitor such as entacapone in the Composition. However, Virkki et al. teaches entacapone in treating Parkinson's disease along with Levodopa and Carbidopa (abstract).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to add Entacapone in the composition provided by Conte et al. because Entacapone helps in treating Parkinson's disease. A skilled artisan would thus have been motivated to formulate a composition comprising Carbidopa, Levodopa and Entacapone to treat Parkinson's disease with a reasonable expectation of success. With respect to the various dosage amounts claimed in claims 9-12, it is the position of the examiner that optimization of such a parameter would have been within the purview of a skilled artisan at the time the invention was made by doing experimental manipulations. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

8. Applicant's arguments filed 09/28/2007 have been fully considered but they are not persuasive.

Applicant argues that the combination of Conte's reference and Vikki's reference would not have suggested the claimed release profiles. this argument is not persuasive because as discussed above, Conte's reference provides various release profiles comprising immediate and controlled release, comprise the same components such as carbidopa and levodopa and the invention is in the same field of endeavor , therefore, optimization of the release profiles would have been obvious in view of the reference and the combination of entacapone in the composition would have been obvious in view of Virkki's reference which teaches that entacapone helps in the treatment of Parkinson's disease. It should be noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit 1615

/S Kishore/

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